Preferred Drug List (PDL) Process for Reviewing New Drugs Approved by the Food and Drug Administration

As the Food and Drug Administration (FDA) approve new drug products, the following process will be utilized for review of the drug product for inclusion on the Preferred Drug List (PDL):

- 1. If the new drug product belongs in a class of drugs that has been previously reviewed by the Pharmacy and Therapeutics (P&T) Committee, the drug will be classified as non-preferred and will require prior authorization in order to be dispensed.
 - a. The P&T Committee will evaluate the drug for clinical effectiveness and safety at the next review of the drug class.
 - b. If the P&T Committee determines that the new drug represents a substantial breakthrough in therapy, then the P&T committee can review the drug at the next scheduled P&T meeting.
 - c. The Committee will review appropriate studies and publications as part of the decision process. In addition the Committee will be provided with information such as disease categories and demographics on the affected Medicaid population in order to assess the potential impact on the population. If the drug meets clinical efficacy and safety standards, the Committee will request applicable pricing information. Based on clinical information and pricing standards, the P&T Committee will determine if the drug will be included in the PDL or require prior authorization.

Drug product line extensions (ex. a new strength of a drug product already included on the PDL) will be reviewed by DMAS who will determine if a class or drug review by P&T Committee is necessary.

2. If the new drug product does not fall within a drug class previously reviewed by the P&T Committee, the Department of Medical Assistance Services (DMAS) will make the determination as to whether the drug requires P&T Committee review.

First Health Services Corporation will be responsible for informing DMAS of any new drug products and providing relevant clinical information on the new drug.

This process was approved by the Pharmacy and Therapeutics Committee on January 6, 2004.